

Testimony of
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before the
House Government Reform Committee
on
Integrative Cancer Care
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Chairman Burton, Congressman Waxman, distinguished Committee members, thank you for inviting us to discuss Medicare coverage for alternative and experimental therapies, as well as efforts to address racial disparities in health care.

The Social Security Act authorizes Medicare coverage of defined categories of medical services provided by specific types of practitioners when such treatments are **Areasonable** and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. @It authorizes the Health & Human Services Secretary to specify what is covered and under what circumstances, and we try to strike the appropriate balance between providing timely access to medical advances and ensuring that treatments are **Areasonable** and necessary. @To do so, we rely on scientific evidence, including medical literature and data, discussions with medical experts, and technology assessments.

We are well aware of the increasing integration of alternative therapies into conventional treatment for patients with cancer and other conditions. I have referred my own patients for treatments such as acupuncture. Hospices, hospitals, and managed care plans in Medicare can provide alternative treatments under discretion they have through per diem, prospective, and capitated payment systems, respectively. And the law specifically provides for Medicare coverage of chiropractic spinal manipulation by chiropractors, as well as massage therapy by physical therapists when the treatment can be demonstrated to help improve a patients health status.

For other alternative therapies, we will move quickly to provide coverage throughout Medicare when there is sufficient scientific evidence to meet the statutory requirement that Medicare fee-for-service treatments be reasonable and necessary.

Coverage for alternative modalities to date has been limited because of the paucity of reliable scientific evidence to support their use. Without such scientific evidence, we are limited in our ability to determine that these treatments meet the statutory requirement of being **Areasonable** and necessary. @However, thanks to the work of my colleague Dr. Straus and others at the National Center for Complementary and Alternative Medicine, as well as work by colleagues at the Agency for Healthcare Research and Quality (AHRQ) and elsewhere, we may be better able to make these determinations soon.

For experimental therapies, Medicare historically has not covered them because they do not meet the requirement of being reasonable and necessary. However, as the President announced this morning, we

have reviewed our legal authority and determined that we can cover the routine services provided to Medicare beneficiaries who are participating in clinical trials. We will move quickly to implement this new policy by formally and explicitly instructing our contractors to provide such coverage. We also will launch education efforts to make sure beneficiaries and providers know that they are entitled to such coverage.

Our new, open and accountable coverage determination process will help facilitate prompt coverage determinations for all experimental and alternative treatments as scientific evidence of their efficacy becomes available. This new process, implemented last year after extensive review of how we could improve our coverage determination process, allows any member of the public to request a coverage determination or submit new evidence that might justify a redetermination. There are time lines for action on such requests, data are reviewed by expert panels in open meetings. The status of determination proceedings is posted on the Internet. And we will work with our National Institutes of Health colleagues to help researchers design trials to evidence needed for coverage determinations, which should help to further speed up the approval process.

We also have several initiatives underway to address racial disparities in care. And we look forward to working with our NIH colleagues to develop a comprehensive strategy to address this important issue.

NEW COVERAGE DETERMINATION PROCESS

The new coverage process helps ensure that the public is fully informed and can track the status of any determination under consideration. We now publish on our *www.hcfa.gov* web site:

- a list of coverage issues under review;
- the stage of review each issue is in;
- the major scientific questions that need to be resolved prior to a coverage decision;
- an estimate of when the next action will occur;
- a complete, indexed record of issues reviewed for each decision, including evidence examined, major steps taken in the review, and the rationale for decisions.

Any member of the public may request a review of a national coverage policy determination at any time. Individuals requesting such a review need only submit the request in writing, along with new medical and scientific evidence that merits consideration, or an analysis of Medicare's decision demonstrating that a material misinterpretation was made in the evaluation of evidence. We also regularly review new medical and scientific information on our own initiative to assess whether modifications to national coverage policy may be appropriate.

We generally respond within 90 days to a coverage review request by:

- referring the request to the new Medicare Coverage Advisory Committee;
- referring the request to an independent technology assessment body, such as those that contract with the Agency for Health Care Research and Quality;
- notifying the requester that coverage is warranted and will be granted;
- notifying the requester that coverage is not warranted and will not be granted;
- notifying the requester that coverage is warranted, but only under certain limitations;
- notifying the requester that coverage will be left to local contractor discretion;

- notifying the requester that the request duplicates and will therefore be combined with another pending request; or
- notifying the requester that the request duplicates an earlier request for which a decision has already been rendered and available evidence does not warrant reconsideration.

The coverage determination process features a Medicare Coverage Advisory Committee which reviews requests in open public meetings. Its 120 members include nationally recognized experts in a broad range of medical, scientific and professional disciplines, as well as consumer and industry representatives.

The Committee is divided into six panels, organized to roughly parallel Medicare benefit categories:

- Medical and Surgical Procedures;
- Laboratory and Diagnostics Services;
- Drugs, Biologics, and Therapeutics;
- Medical Devices and Prosthetics;
- Durable Medical Equipment; and
- Diagnostic Imaging.

Each panel includes a consumer representative and an industry representative. These panels review and evaluate medical literature, technology assessments, and other data on the effectiveness and appropriateness of medical items and services. Based on the evidence reviewed, the Committee advises and makes recommendations to HCFA.

We are now beginning to use this new process to review whether acupuncture meets the reasonable and necessary criteria for coverage. Since our agency testified before you last fall, we have thoroughly reviewed all the studies cited in the National Institutes of Health Consensus Conference report on acupuncture. The report concluded that scientific evidence suggests that acupuncture is promising for several conditions, including treatment of chemotherapy related nausea. Our extensive analysis of literature cited in the NIH consensus report will serve as the starting point in the coverage determination process, and we are making an open request for any and all additional scientific data.

Coverage Criteria

To further improve and clarify our coverage process, last month we issued a *Federal Register* notice proposing to develop national criteria for whether a service or treatment meets the reasonable and necessary requirement. The notice describes two criteria that could be applied:

- **Medical Benefit.** An item or service is shown through objective clinical evidence to have medical benefit -- i.e. produce a health outcome better than the natural course of illness or disease with customary medical management of symptoms; and
- **Added Value.** An item or service provides added value compared to existing treatments -- i.e. it substantially improves health outcome, provides access to a beneficial treatment of a different type (medication instead of surgery), or substitutes for an existing treatment at lower cost.

The notice invites public comment, which may be received through June 15. Public comments will be considered in the drafting of a proposed rule. The public will then have an additional opportunity to

comment on the criteria before they become final.

CLINICAL TRIAL COVERAGE

This morning the President announced that we will change Medicare policy to explicitly authorize coverage for routine patient care costs provided to Medicare beneficiaries participating in clinical trials. Before today, Medicare reimbursement policies often discouraged seniors from participating in clinical trials. Because clinical trial investigators could not guarantee that Medicare would pay for the routine care associated with participation in their clinical trial, seniors considering whether to enter these trials had to assume that they may be responsible for costs simply because they were participating in a clinical trial. In addition, investigators and research centers were often reluctant to recruit them because of the uncertainty of Medicare coverage.

Promoting biomedical research and ensuring that Medicare beneficiaries receive the highest quality care possible are longstanding priorities for this Administration. And we have been greatly concerned that only about one percent of seniors now participate in clinical trials, even though the elderly are most likely to have conditions being studied.

For cancer, seniors constitute 63 percent of cases but only 25 percent of those in clinical trials. For breast cancer the disparity is worse. Half of all patients are seniors, but seniors represent less than 2 percent of those in clinical trials.

These low participation rates hinder development of new therapies, as it often takes between 3 and 5 years to enroll enough participants in a trial. In fact, one reason for the stunning advances in pediatric cancer care has been that more than half of pediatric cancer patients were enrolled in clinical trials over the last twenty years, and today, 75 percent of cancers in children are curable.

To address these problems, the President has instructed us to:

- Immediately revise Medicare program guidance to explicitly authorize coverage for routine patient care costs and costs due to medical complications arising after trials.
- Inform beneficiaries and providers about this new coverage option.
- Help researchers design trials to produce data needed for Medicare coverage decisions.
- Review the feasibility and advisability of additional action to promote research, including:
 - providing financial support for monitoring, evaluation, and other non-routine, non-covered costs for those trials of particular relevance to Medicare beneficiaries;
 - establishing a system to track spending in trials that Medicare supports; and
 - exploring further efforts to increase participation of seniors in clinical trials and ensure that researchers can determine the best therapies for older as well as younger patients.

ADDRESSING RACIAL DISPARITIES

We are working diligently to address disturbing disparities in access to care, morbidity, and mortality among racial and ethnic minorities. As President Clinton said when announcing his goal to eliminate disparities by 2010: We do not know all the reasons for these disturbing gaps. Perhaps inadequate education, disproportionate poverty, discrimination in the delivery of health services, and cultural differences are all contributing factors.

But we do know this: no matter what the reason, racial and ethnic disparities in health are unacceptable in a country that values equality and equal opportunity for all. And that is why we must act now with a comprehensive initiative that focuses on health care and prevention for racial and ethnic minorities.@

At HCFA, we co-sponsored a conference last fall that brought together leading researchers to help us develop a research agenda on what causes disparities and what helps in eliminating them. Papers we commissioned at the conference should be published later this year. We also have new contracts with Medicare's physician-led Peer Review Organizations that include projects with local groups to reduce disparities. And we have many initiatives that concentrate on making health care and health care information understandable and attainable for all populations.

For example, our HORIZONS program targets African-American, Hispanic, Asian-American and Pacific Islander, and American Indian and Alaska Native beneficiaries as we work to overcome language and cultural barriers that inhibit these groups from understanding and receiving health care and information. We also are working with the Office of Minority Health to improve our health communication efforts and to develop strategies to reach vulnerable and underserved populations. And we are working to increase the materials translated into other languages on our *www.medicare.gov* beneficiary web site; currently, information on Medicare contacts, quality comparisons, and other useful resources is available in Spanish and Chinese on the web site.

Furthermore, the latest versions of our final Medicare+Choice regulations and the final Quality Improvement System for Managed Care Standards and Guidelines considerably expand cultural competency requirements. A growing body of knowledge demonstrates that when care is provided in both a clinically competent and culturally appropriate fashion, it is more readily understood and accepted by the patient. A key part of cultural competency is recognizing and respecting use of traditional treatments and beliefs, and working to integrate them into conventional medical care. As a result, patient compliance is enhanced, outcomes are improved, and health care costs and expenses are reduced by diminished illness and mortality.

Our efforts not only enable these populations to better understand Medicare and Medicaid materials, but they help us to receive survey information and other feedback from these populations, further enhancing our ability to provide the information and care they need.

Beyond producing materials that can be understood by a broader range of people, we are striving to put these materials in the hands of beneficiaries, especially those in underserved populations. Our Regional Education About Choices in Health (REACH) campaign is the localized outreach component of the National Medicare Education Program. It has activities tailored to reach minority groups using demographic maps and partnering with local organizations that represent these groups. It concentrates on educating beneficiaries on basic Medicare and their options under the Medicare+Choice program, as well as raising beneficiary awareness of our information channels, including Medicare.gov and 1-800-MEDICARE.

In addition to these communication efforts, for the last two fiscal years we have been working with the Indian Health Service to establish cost reporting for its 49 hospitals. While Medicare is moving to prospective payment systems, cost reports may remain the final claim for payment in Medicaid. Prior to our involvement, these facilities were not filing any cost reports for either Medicare or Medicaid. We have been working to enhance their reporting capabilities so they can receive Medicaid payment, and so far, 16 of the 49 hospitals are filing annual cost reports. We plan to continue working until all 49

hospitals are completing cost reports.

Communications and payment are important, but we also are working to improve minority involvement in the health care system. Beyond our own equal opportunity programs, we serve as training site for a number of the fellows in the American Association of Health Plans=Minority Management Development Program. The Program is designed to expand the number of minority managers and executives in managed care organizations. In FY 2000, three Program fellows participated in a six-week rotation at the HCFA central office and two fellows performed a similar rotation in our California regional office.

All of our initiatives are taking place within the broader context of the President's goal of eliminating longstanding racial health disparities. The Department of Health and Human Services has worked to close these gaps in health through a plan that sets a national goal of eliminating health disparities in six primary areas by the year 2010. These areas include: infant mortality; cancer screening and management; cardiovascular disease; diabetes; HIV/AIDS rates; and child and adult immunization levels.

The Department's initiatives are spearheaded by a sweeping outreach campaign led by Surgeon General David Satcher. This includes developing new approaches and encouraging local, innovative strategies to address racial and ethnic health disparities. We also are developing a new Foundation/Public Sector collaboration to work on this initiative, and we are looking at more effective ways to target existing federal programs to address health disparities. Perhaps most importantly, the Department has issued a challenge to involve communities, foundations, advocacy organizations, and businesses in developing strategies to diminish these gaps in health. With a collaborative, national focus on this important issue, we are moving towards raising the health levels of all Americans **B** we are moving in the right direction.

CONCLUSION

We greatly appreciate the desire of this Committee for wider coverage of alternative and experimental therapies, and steps to address racial disparities in care. We will continue to work closely with the NIH to develop the scientific knowledge we need for coverage of alternative therapies. We will move quickly to implement the new clinical trials coverage policy announced today by the President. And we are committed to working to address racial disparities in care. I thank you for holding this hearing, and I am happy to answer your questions.

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